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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/618,129	07/17/2000	Xiao Bing Wang	TRIM1	8510
24504	7590	09/23/2003		
THOMAS, KAYDEN, HORSTEMEYER & RISLEY, LLP 100 GALLERIA PARKWAY, NW STE 1750 ATLANTA, GA 30339-5948			EXAMINER	
			SPIEGLER, ALEXANDER H	
			ART UNIT	PAPER NUMBER
			1637	
DATE MAILED: 09/23/2003				<i>27</i>

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/618,129	WANG, XIAO BING
	Examiner	Art Unit
	Alexander H. Spiegler	1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 22 April 2003.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 2-9,11-37 and 39-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 2-9,11-37 and 39-41 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>8,192426</u> . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Status of the Application

1. This action is in response to Paper No. 23, filed on April 22, 2003. Currently, claims 2-9, 11-37 and 39-41 are pending and are rejected. All arguments have been fully considered and thoroughly reviewed, but are deemed not persuasive for the reasons that follow. This action is made FINAL. Any objections and rejections not reiterated below are hereby withdrawn. Specifically, the 102 and 103 rejections in view of Applied Genetics (WO 96/30545) have been withdrawn in view of Applicants amendments and arguments.

Information Disclosure Statement

2. The information disclosure statement of Paper Nos. 8, 19, 24 and 26 comply with CFR 1.97, 1.98, and M.P.E.P. 609, and have been considered (see enclosed signed PTO-1449s). However, references AJ (filed on 9/10/01) and L, M and P (filed on 7/21/03) have not been considered because they did not appear in the application file.

MAINTAINED REJECTION

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 2-9, 11-37 and 39-41 are rejected under 35 U.S.C. 102(e) as being anticipated by Soderlund (US 6,013,431).

Regarding Claims 2-3, 5-6, 37 and 39-41, Soderland teaches a method for detecting a target nucleic acid comprising:

- (a) providing a detectable amount of a target nucleic acid polymer in a single stranded form,
- (b) hybridizing the detectable amount of the nucleic acid polymer with one or more oligonucleotide primers (forming a primer-nucleic acid duplex), wherein each primer has a nucleotide sequence that is complementary to a sequence in the target nucleic acid polymer, such that when the primer is hybridized to the target nucleic acid polymer, the 3' end of the primer binds to a nucleotide flanking the specific nucleotide at the defined site in the target nucleic acid (i.e. the first unpaired base immediately downstream of the 3' end of the primer),
- (c) exposing the hybridized nucleic acid polymer to a polymerization agent in a mixture containing at least one deoxynucleotide, said deoxynucleotide comprising a detectable label, and one or more chain terminating nucleotide analogues, such that a detectable primer extension product is formed if the labeled deoxynucleotide is complementary to the specific nucleotide at the defined site, and
- (d) analyzing the polymerization mixture of step (c) for the presence or absence of the primer extension product containing the labeled deoxynucleotide at the 3' end thereof, whereby the identity of the specific nucleotide at the defined site is determined (See col. 7-8, Examples 1-7, and col. 18, ln. 19-53, for example).

Regarding Claim 4, Soderlund teaches the target nucleotide is defined as any known base (See col. 3, ln. 39-41, col. 4, ln. 59-63, col. 5, ln. 26-32, for example)

Regarding Claim 7, Soderlund teaches the terminator can be labeled with a detectable marker which is different from the marker on the non-terminator (See col. 7-9, for example)

Regarding Claim 8, Soderlund teaches that two or more differently labeled dNTPs (non-terminator nucleotides) can be added to the primer-nucleic acid duplex, wherein the detection is better interpreted by adding dNTPs that are different than the terminator nucleotide (See col. 8, ln. 58-64, for example).

Regarding Claim 9, Soderlund teaches the use of this invention with various labels such as radioactive or fluorescent labels (see examples 1-7, col. 9-18, for example).

Regarding Claims 11-14, Soderlund teaches that the primer extension reaction can be performed by enzymatic means using template dependent enzymes (i.e. T7 DNA polymerase, T4 DNA polymerase, reverse transcriptase, etc.) (col. 8, ln. 10-17, for example).

Regarding claims 15-22, Soderlund teaches that the primer may contain an attachment moiety (i.e. biotin, antigens, etc.) (See col. 6, ln. 16-31, for example), that permits affinity separation of the from the unincorporated reagent and/or the nucleic acid of interest (col. 6, ln. 53 to col. 7, ln. 26, for example), and furthermore, that a solid support may be used in the separation process (col. 6-7, for example).

Regarding Claims 23-36, Soderlund teaches the source of the target nucleic acid of interest can be any form of RNA or DNA obtained via amplification (for example), from any source such as from a human, animal, plant, or microbe (See cols. 1-5 and Examples 1-7).

With respect to Applicants amendment of Claim 37 and newly added claims 39-41, Applicants have amended the claims to recite, “known wild-type” and “mutant target nucleotide”. However, the terms “wild-type” and “mutant” are relative terms, which can be

population specific. That is, these terms are not fixed terms, wherein in one population a specific nucleotide may be considered “wild-type”, but in a different population the specific nucleotide may be considered “mutant”. Soderlund teaches the detection of variant nucleotides, wherein these variant nucleotides, depending on the population, could be considered “wild-type” or “mutant”. Accordingly, the recitations of “wild-type” and “mutant” do not distinguish the present invention from the teachings of Soderlund.

Response to Applicants Arguments

The Soderland '431 patent entitled, “Method for determining specific nucleotide variations by primer extension in the presence of mixture of labeled nucleotides and terminators” is based on a method of determining unknown bases. Applicants patent application entitled, “Detection of sequence variation of nucleic acid by shifted termination analysis” also seeks to determine the identity of an unknown base at a predetermined location. These methods are general methods used to determine a nucleic acid of interest.

Applicants argue that the newly amended recitations of “known wild-type” and “mutant” target nucleotides distinguish the methods of the present invention from that of Soderlund. However, as discussed above, the terms “wild-type” and “mutant” are relative terms, which can be population specific. That is, these terms are not fixed terms, wherein in one population a specific nucleotide may be considered “wild-type”, but in a different population the specific nucleotide may be considered “mutant”. Soderlund teaches the detection of variant nucleotides, wherein these variant nucleotides, depending on the population, could be considered “wild-type” or “mutant”. Accordingly, the recitations of “wild-type” and “mutant” do not distinguish the present invention from the teachings of Soderlund.

For these reasons, and those of record, the rejection is maintained.

Conclusion

5. No claims are allowable.
6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

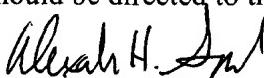
Cantor et al. (USPN 6,007,987)

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander H. Spiegler whose telephone number is (703) 305-0806. The examiner can normally be reached on Monday through Friday, 7:00 AM to 3:30 PM.

If attempts to reach the examiner are unsuccessful, the primary examiner in charge of the prosecution of this case, Carla Myers, can be reached at (703) 308-2199. If attempts to reach Carla Myers are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax number for the organization where this application or proceeding is assigned is (703) 872-9306. Applicant is also invited to contact the TC 1600 Customer Service Hotline at (703) 308-0198.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Alexander H. Spiegler
September 17, 2003


CARLA J. MYERS
PRIMARY EXAMINER